REMARKS

Reconsideration of amended claims 1, 3, 5-7 and 18-27 is respectfully requested. Claims 22 and 27 are amended. A Declaration under 37 C.F.R. § 1.132 of Brien C. David is submitted with this Amendment.

The rejection of claims 1, 3, 5-7, 20-22, 24, 26 and 27 under 35 USC 103(a) as unpatentable over Groemminger (US2002/0115578) in view of Asgharian (US 6228323) is respectfully traversed. Groemminger describes compound components that are used in contact lens care solutions. These components include the poloxomer and poloxamine surfactants and the disinfectant, poly(hexamethylene biguanide) (PHMB) within the recited concentration range. As recognized by the examiner, Groemminger does not describe the "use of a polyethylene terephalate container" to package or store contact lens care solutions.

The examiner cites Asgharian to overcome the recognized deficiency in Groemminger. The examiner asserts that the "article of manufacture as suggested by Groemminger", that is, the contact lens solution containing PHMB and poloxamine surfactants, "in combination with Asgharian" that is, use of a container comprised of polyethylene terephalate (PET) to store a contact lens solution that contains polyquaternium-1 or PHMB, and poloxamine (i.e., Tetronic®1304) is *prima facie* obvious. The examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to package the [lens care] compositions taught by Groemminger in a polyethylene terephalate container, … because Asgharian et al teaches the use of a polyethyleneterephalate container to package similar contact lens cleaning/disinfecting compositions." Applicants agree with the examiner's legal conclusion that the cited combination of Groemminger and Asgharian presents a *prima facie* case of obviousness.

To rebut the *prima facie* case, Applicants submit the Declaration of Brien C. David. Mr. David supervises the microbiological group at Bausch & Lomb (B&L). As indicated by the biocidal stability data of test solution 1 and the conclusions stated in the Declaration of Brien David, the solution exhibits a huge difference in shelf-life depending upon which type of container the solution is stored. As evident by the biocidal data, these differences with respect to three of the five microorganisms required by the Federal Drug Administration (FDA) are quite large and

clinically significant. For example, at three months at 40 °C, there is statistically no change in the biocidal efficacy of test solution 1 in the PET container. In contrast, there is a greater than 100-fold reduction against *Fusarium solani,* of test solution 1 in HDPE at three months at 40 °C.

More dramatic results are indicated with the biocidal stability data for six months at 40 °C for test solution 1 in PET and HDPE containers. There is at least a 10-fold reduction against *Candida albicans*, a 100-fold reduction against *Staphylococcus arueus* and a 1000-fold reduction against *Fusarium solani*. Test solution 1 would fail ISO(FDA) at six months (40 °C) with respect to two of the five microorganisms. In contrast, test solution 1 packaged in PET exhibits only a 10-fold reduction against *Fusarium solani*. Given this test data Applicants respectfully submit the examiner's *prima facie* case of obviousness has been rebutted, and request that the rejection be withdrawn.

The rejection of claims 1, 3, 5-7, 19-22 and 24-27 under 35 USC 103(a) as unpatentable over Bhatia et al. (US 6171404) in view of Stone et al. (US 2002/0039975) and WO 99/43363 is respectfully traversed. Given the highly unexpected differences indicated in the biocidal data and the conclusions drawn from the data and stated in the 132 Declaration of David, Applicants submit that any alleged *prima facie* case of obviousness has been rebutted. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Furthermore, each cationic-nitrogen disinfectant is sufficiently different in chemical structure and microbiocidal efficacy. These differences do affect the biocidal effectiveness of a given lens care solution – all other components being the same. Also, one disinfectant may be more sensitive to plastic additives found in containers than others. On page 8 of the official action, the examiner comments on the equivalence of PHMB and polyquaternium-1, and that one of ordinary skill could interchange these two disinfectants without affecting the biocidal properties of a particular solution. Without knowledge or information to the contrary one would tend to agree with such as assumption.

In practice, however, the chemical realities of these different disinfectants do provide a substantial amount of chemical and biological unpredictability. In practice, the mere substitution of one disinfectant agent for another, even within the same chemical class, provides a solution with a different chemical and/or biocidal profile. For example, one skilled in the art of developing

contact lens solutions knows that polyquaternium-1 is not as effective against fungi as PHMB. It is for this reason, that OptiFree Express and OptiFree Replenish each contain a supplemental disinfectant agent to combat the fungi. Also, if one looks to the data reported in the application itself, one would recognize that alexidine, which like PHMB is a biguanide disinfectant agent, is not affected by the plastic additives found in HDPE. In other words, there is no difference in the shelf-life or biocidal stability of test solution 2 (see, page 14 of the application) if the solution is packaged and stored in PET or HDPE.

For the reasons stated, Applicants respectfully request that the rejection be withdrawn.

Dated: October 15, 2008

Respectfully submitted,

Joseph Barrera
Registration No. 44,522

BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester, NY 14604-2701
Telephone: (585) 338-8180
Facsimile: (585) 338-8706